

Biophor Diagnostics, Inc.  
Traditional Premarket Notification 510(k) Submission: K122703  
RapidFRET Oral Fluid Assay for PCP

**510(k) Summary for the RapidFRET Oral Fluid Assay for PCP**

**APR 25 2013**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is:

**807.92(a)(1): Contact Information**

Name: Biophor Diagnostics, Inc.  
Address: 1201 Douglas Avenue  
Redwood City, CA 94063

Contact: Nathaniel G. Butlin, Ph.D.  
Phone: 650-367-4954  
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Date prepared: April 23, 2013

**807.92(a)(2): Device Name, Common Name and Classification**

RapidFRET Oral Fluid Assay for PCP (Enzyme Immunoassay for Phencyclidine)  
RapidFRET Oral Fluid PCP Calibrator Set (Clinical Toxicology Calibrator)  
RapidFRET Oral Fluid PCP Control Set (Drug Mixture Control Materials)  
RapidEASE Oral Fluid Collector  
RapidFRET Integrated Workstation

Product	Code	Class	Regulation Section	Panel
RapidFRET Oral Fluid Assay for PCP	LCM	II	862.3100	91 - Toxicology
RapidFRET Oral Fluid PCP Calibrator Set	DKB	II	862.3200	91 - Toxicology
RapidFRET Oral Fluid PCP Control Set	DIF	I	862.3280	91 - Toxicology

**807.92(a)(3): Identification of Legally Marketed Predicate Devices**

Thermo Scientific CEDIA® Phencyclidine (PCP) OFT Assay (k101746).

**807.92(a)(4): Device Description**

The RapidFRET Oral Fluid Assay for PCP is an In Vitro Diagnostic competitive immunoassay used to detect PCP in human oral fluid. This is a ready-to-use homogenous system that involves energy transfer between an acceptor fluorophore labeled to an antibody and a donor fluorophore labeled to drug. The assay is based on competition between drug in the sample and drug labeled with the donor fluorophore for a fixed number of binding sites on the antibody reagent. When acceptor and donor fluorophores are brought into close proximity through a binding event, energy transfer occurs. The fluorescence resonance energy transfer (FRET) signal is measured at the wavelength of the acceptor fluorophore and is inversely

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RapidFRET Oral Fluid Assay for PCP

proportional to the amount of drug in the sample. A Cutoff Calibrator is used to translate the sample measurement into a positive or negative result. Controls are used to establish and monitor precision and accuracy. The assay is performed on the RapidFRET Integrated Workstation.

**807.92(a)(5): Intended Use**

The RapidFRET Oral Fluid Assay for PCP is a homogeneous time-resolved fluorescence assay that is intended for prescription use in central laboratories only on the RapidFRET Integrated Workstation. The assay is used to perform a qualitative screen for Phencyclidine at 10 ng/mL in neat oral fluid samples collected with the RapidEASE Oral Fluid Collector. This assay provides only a preliminary result. To obtain a confirmed analytical result, a more specific alternate chemical method such as GC/MS or LC/MS/MS is required. Professional judgment should be applied to any drug test result, particularly when using preliminary positive results. For In Vitro Diagnostic Use Only.

The RapidFRET Oral Fluid PCP Calibrator Set and RapidFRET Oral Fluid PCP Control Set are intended for use only with the RapidFRET Oral Fluid Assay for PCP and samples collected with the RapidEASE Oral Fluid Collector. The cutoff calibrator is used to determine the cutoff level and translate the assay measurement into a positive or negative result. The positive and negative controls are used to monitor laboratory systems, operators, precision, accuracy and assay conditions. For In Vitro Diagnostic Use Only.

**807.92(a)(6): Technological Similarities and Differences to the Predicate**

	Thermo PCP	RapidFRET PCP
Indications for Use	Qualitative determination of phencyclidine in human oral fluid.	Same
Methodology	Homogeneous competitive immunoassay.	Same
Kit Components	1 PCP specific antibody reagent (marketed in combination as a lyophilized reagent and reconstitution buffer). 1 PCP drug conjugate reagent (marketed in combination as a lyophilized reagent and reconstitution buffer).	1 PCP specific antibody reagent in liquid, ready to use format. 1 PCP drug conjugate reagent in liquid, ready to use format.
Controls	4 different Control and Calibrator concentrations are available for qualitative screens.	Same
Calibrators	2 Calibration levels are available.	Same

Performance Characteristics	Precision, accuracy, cross reacting/interfering studies are similar to the RapidFRET Oral Fluid Assay for PCP	Precision, accuracy, cross reacting/interfering studies demonstrate equivalence to the predicate devices
Safety and Effectiveness	Demonstrated in bench testing and described in PI.	Demonstrated in bench testing and described in PI, equivalent to predicate.
Neat Oral Fluid Cutoff Level	3 ng/mL neat oral fluid.	10 ng/mL neat oral fluid.
Platform	MGC240 analyzer	RapidFRET Integrated Workstation
Sample Collection	Oral fluid is collected with the Oral-Eze Saliva Collection System. This device uses an absorbent swab and diluent. Sample is stored in plastic tube with snap cap.	Neat oral fluid is collected with the RapidEASE Oral Fluid Collector via direct expectoration. No diluent is used and sample is stored in glass sample tube with inert screw cap.
Principle and Procedure	<p>The assay is based on the sample analytes competing with analyte conjugates to one inactive fragment of <math>\beta</math>-galactosidase for antibody binding sites.</p> <p>The amount of drug in the specimen is inversely proportional to the assay signal as measured by absorbance.</p>	<p>Drugs in the oral fluid sample compete with the PCP conjugate donor fluorophore for a fixed number of binding sites on the individual drug antibody acceptor reagents. When acceptor and donor fluorophores are brought into close proximity, through the binding event, fluorescent energy transfer is measured.</p> <p>The amount of drug in the specimen sample is inversely proportional to the assay signal as measured by time resolved fluorescence.</p>
Controls and Calibrator Levels	Calibrators are available at 0 ng/mL, 1 ng/mL, 3 ng/mL and 20 ng/mL.	Calibrators are available at 0 ng/mL and 10 ng/mL. Controls are available at 5 ng/mL and 15 ng/mL.

**807.92(b)(1): Brief Description of Study Data:**

A series of studies were performed that evaluated the device performance characteristics including precision and analytical sensitivity, correlation with GC/MS, cross reactivity, and analytical specificity that are summarized below.

***Precision***

Three lots of the RapidFRET Oral Fluid Assay for PCP were analyzed, four times daily, for a minimum of 20 days. Negative oral fluid pools were spiked with PCP at 0%, 25%, 50%, 75%, 100%, 125%, 150%, 175% and 200% of the cutoff level corresponding to approximately 0, 2.5, 5.0, 7.5, 10, 12.5, 15.0, 17.5 and 20 ng/mL. The aggregate data is summarized in the

table below:

PCP	0%	25%	50%	75%	100%	125%	150%	175%	200%
POS	0	0	0	0	2	278	263	294	278
NEG	279	278	279	279	277	0	0	0	0
N	279	278	279	279	279	278	263	294	278

#### ***Correlation with GC/MS***

Neat oral fluid was collected with the RapidEASE Oral Fluid Collection Device from volunteers potentially positive and negative for PCP. The samples (n=246) were randomized and blinded to the instrument operator and assayed using RapidFRET PCP reagents. Following screening, positive and negative samples were sent to a reference laboratory for confirmatory testing. The summarized data are shown below.

n = 246	GC/MS POS	GC/MS NEG
RapidFRET POS	119	1 <sup>†</sup>
RapidFRET NEG	0	126
% Agreement	100%	99%

<sup>†</sup>Sample contained 9 ng/mL PCP by GC/MS.

The data indicate that the RapidFRET Oral Fluid Assay for PCP was accurate >99% of the time in neat oral fluid samples collected with the RapidEASE Oral Fluid Collector.

#### ***Cross Reactivity and Analytical Specificity***

A compound library of 175 different structurally related and unrelated compounds including metabolites, OTC and prescription medications and drugs of abuse was used to evaluate the device cross reactivity and specificity. Compounds were spiked at 30,000 ng/mL into neat oral fluid pool aliquots with 0 ng/mL, 5 ng/mL and 15 ng/mL PCP, processed with the RapidEASE Collector, and tested with the RapidFRET PCP assay. Those compounds that gave an unexpected result were further titrated to determine the concentration at which the cross-reacting compound yielded a result approximately equivalent to the cutoff. Only 4-HydroxyPCP and PCM were found to cross react below 10,000 ng/mL with cutoff equivalent concentrations determined to be 620 and 310 ng/mL, respectively, in the absence of PCP.

A second study evaluated common substances such as foods and dental products as well as pH variations. HSA, ethanol, baking soda, whole blood, hemoglobin, hydrogen peroxide, sodium chloride, cholesterol, denture adhesive, ascorbic acid, bilirubin, IgA, IgG and IgM were spiked into neat oral fluid pool aliquots that contained either 5 ng/mL or 15 ng/mL PCP. Neat oral fluid pool was titrated to pH values of 5, 6, 7, 8 and 9, spiked with PCP at 5 ng/mL or 15 ng/mL and assayed with the RapidFRET PCP Assay. The effects of antiseptic mouthwash, cough syrup, cranberry juice, orange juice, tooth paste, chewing tobacco, cigarettes, chewing gum, hard candy, teeth whitening strips, cola, water, antacid, coffee and tea were evaluated by asking volunteers to use a specific item and provide an oral fluid

sample. These samples were then spiked with PCP at 5 ng/mL or 15 ng/mL, processed with a RapidEASE Collector and assayed with the RapidFRET PCP assay. All compounds at the listed concentrations gave a NEG result when spiked with 5 ng/mL PCP and a POS result when spike with 15 ng/mL PCP.

**807.92(b)(3): Conclusions**

The RapidFRET Oral Fluid Assay for PCP including the RapidFRET Oral Fluid Negative and Cutoff Calibrators, the RapidFRET Oral Fluid Negative and Positive Controls and the RapidEASE Oral Fluid Collector were determined to be safe and effective for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Biophor Diagnostics, Inc.  
C/O Nathaniel G. Butlin  
1201 Douglas Avenue  
REDWOOD CITY CA 94063

April 25, 2013

Re: K122703

Trade/Device Name: RapidFRET Oral Fluid Assay for PCP  
RapidFRET Oral Fluid PCP Calibrator Set  
RapidFRET Oral Fluid PCP Control Set  
RapidEASE Oral Fluid Collector  
RapidFRET Integrated Workstation

Regulation Number: 21 CFR 862.3100

Regulatory Class: Unclassified

Product Code: LCM, DKB, DIF

Dated: April 09, 2013

Received: April 17, 2013

Dear Dr. Butlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Katherine Serrano**

For

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k122703

### Device Names:

RapidFRET Oral Fluid Assay for PCP  
RapidFRET Oral Fluid PCP Calibrator Set  
RapidFRET Oral Fluid PCP Control Set  
RapidEASE Oral Fluid Collector  
RapidFRET Integrated Workstation

### Indications for Use:

The RapidFRET Oral Fluid Assay for PCP is a homogeneous time-resolved fluorescence assay that is intended for prescription use in central laboratories only on the RapidFRET Integrated Workstation. The assay is used to perform a qualitative screen for Phencyclidine at 10 ng/mL in neat oral fluid samples collected with the RapidEASE Oral Fluid Collector. This assay provides only a preliminary result. To obtain a confirmed analytical result, a more specific alternate chemical method such as GC/MS or LC/MS/MS is required. Professional judgment should be applied to any drug test result, particularly when using preliminary positive results. For In Vitro Diagnostic Use Only.

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Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use         
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles  
2013.04.24 14:06:21-04:00

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)   k122703